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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/730,456

12/08/2003

Robert G. Metzger

5490-000317

2923

27572 7590 01/30/2008  
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EXAMINER
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SWIGER III, JAMES L

ART UNIT	PAPER NUMBER
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3733

MAIL DATE	DELIVERY MODE
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01/30/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

### Application No.

10/730,456

### Applicant(s)

METZGER ET AL.

### Examiner

James L. Swiger

### Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 September 2007.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-9,21,23,25-28 and 34-42 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-9,21,23,25-28 and 34-42 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 May 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

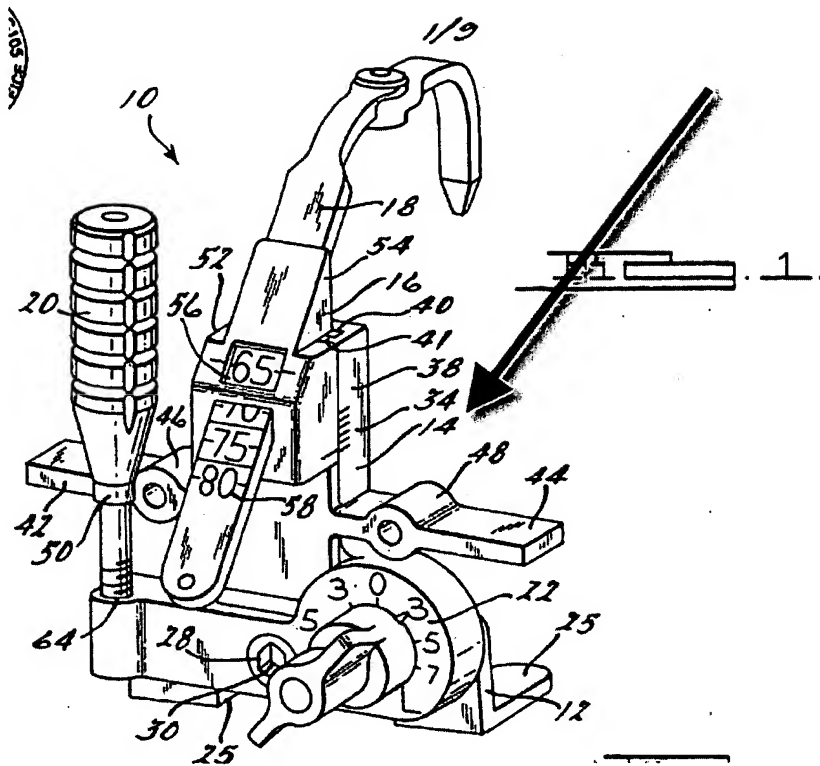
- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_: 6/7/2007.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Drawings***

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "14" has been used to designate a base portion in Figs. 1 and Fig. 2. These are two separate portions denoting the same subject matter and is thus conflicting. See drawings below. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Item 14 defined as base:



Item 14 defined as base:

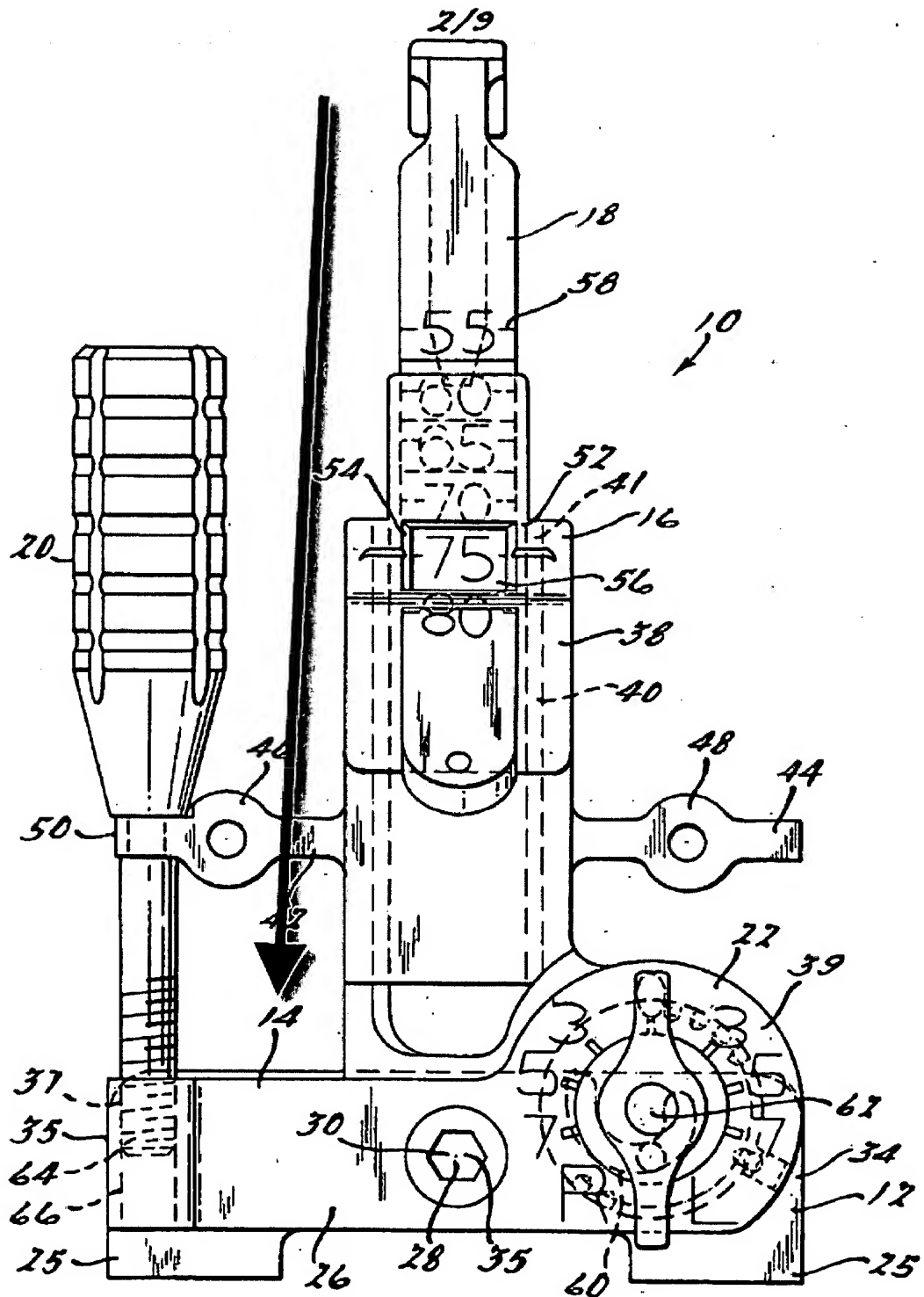


FIG. 2.

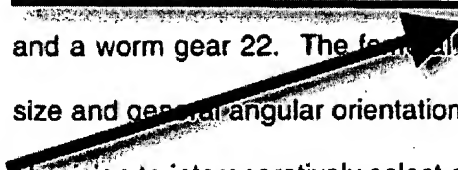
***Specification***

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Applicant has claimed that in independent claims 1, 6, and 34 a first actuator that extends between an extension portion, a foot, or even a member. However applicant has disclosed (as shown below) that the actuator is item 20 as shown in the drawings. According to applicant's specification item 20 does NOT extend between an extension, foot, or member. It extends between a superstructure (16) and a base (14).

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Biomet Ref. B-517/BMT 5333 & B-518/BMT 5334

~~actuator 20 disposed between the superstructure 16 and the base portion 14, and a worm gear 22. The femoral sizing guide 10 is configured to measure the size and general angular orientation of the condyles of a femur to allow a treating physician to interoperatively select a proper femoral prosthetic.~~



It is further noted that as mentioned earlier, item 14 is pointing to TWO DIFFERENT ITEMS in the drawings. In only one instance of the drawings or one of the two options provided by the drawings, could this possibly occur. Thus, the support for these claims is DELIBERATELY MISLEADING.

Disparities between the claims and specification were first mentioned in the office action submitted October 13, 2006. Applicant responded by stating that a "worm gear" can function as an actuator (see response dated 1/16/2007). Though its function as an

actuator may be true, it is not supported by the specification of this case. Further the actuator as claimed is not enabled in light of the actuator as described in the specification.

Appropriate action is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 9, 21 and 35 are rejected under 35 U.S.C. 112, first paragraph, as based on a disclosure which is not enabling. A **second actuator** critical or essential to the practice of the invention, but not included in the claim(s) is not enabled by the disclosure. See *In re Mayhew*, 527 F.2d 1229, 188 USPQ 356 (CCPA 1976).

Claims 9, 21, and 35 rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant has failed to disclose a second actuator disposed between a superstructure and a base. It can ONLY BE ASSUMED that applicant actually means that the actuator (20) as disclosed is the second actuator. However, since only one actuator is taught by the specification, there can be no second actuator to enable the device to function.

Appropriate action is required.

***Claim Rejections - 35 USC § 102***

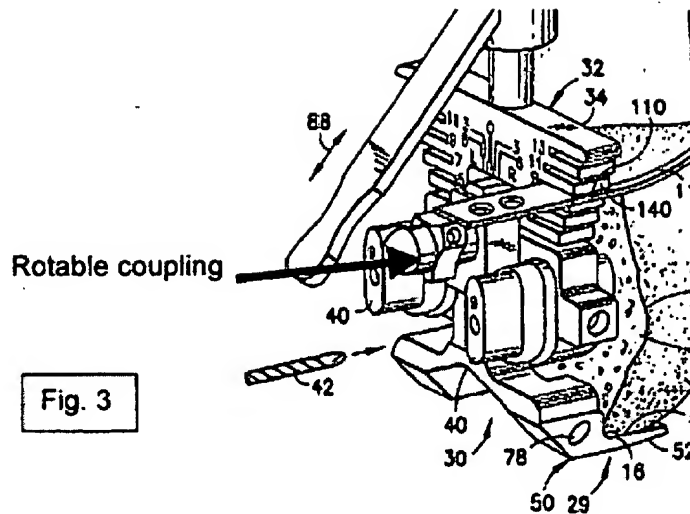
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 8, 34, 36-37, and 41-42 are rejected under 35 U.S.C. 102(b) as being anticipated by Harwin et al. (US Patent 6,458,135). Harwin et al. disclose a femoral guide having an extension portion (30) configured to be adjacent to a posterior condyle surface to the femur, a base portion (32), a superstructure (90) and a graduated stylus (80) that is *configured* to be adjacent to the anterior condyle surface of the femur. It is further noted that language "configured to" has been held that performing a function is not a positive limitation but only requires the ability to perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Harwin et al. further disclose a device with a pair of feet (52, the second foot hidden in Fig. 3), the extension is rotably coupled to the base (See Fig. 3 below)





Contrary to the arguments as disclosed by applicant on 7/24/2006, the Harwin reference DOES teach that the base may be rotably coupled to the base. Harwin discloses that 60 is a "pivotal connection" and further that the device includes (65) markings to better fit various angles. See also Fig. 2, lines 35-50). Further, the device of Harwin et al. disclose a slot to restrain the movement of the stylus (96) that is also capable of being rotably coupled and is substantially parallel.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7 and 38-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Harwin et al. '135 in view of Axelson, Jr. et al. (US Patent 5,860,980). Harwin et al. disclose the claimed invention except for a worm gear disposed between the base and

extension portion that is capable of causing a user-specified amount of movement with respect to the base and extension. Axelson [Axelson] disclose an apparatus with a gear capable of functioning as a worm gear (18), that can provide movement appropriate to the claim language (see also Col. 5, lines 1-9, and line 66 through Col. 6, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Harwin et al. having at least a worm gear in view of Axelson to better adjust and use the device and better fit the condylar portion of the femur.

Claims 9, 21, 23, 28, and 35 rejected under 35 U.S.C. 103(a) as being unpatentable over Harwin in view of Wixon et al. (US Patent 5,624,444). Harwin et al. disclose the claimed invention except for a second actuator, the second actuator being interpreted as a portion that would move a second portion of the sizing guide, such as between a superstructure and a base. Wixon disclose an actuating device (34) that assists in adjusting the device to conform to various anatomies. Disclosed as a knob, it actuates the device that in turn conforms to the bone structure. It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Harwin et al. having at least a second actuator in view of Wixon et al. to better arrange the device in use.

Claims 25-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Harwin et al. '135 and Wixon et al. '444 as applied to claim 21 above, and further in view of Axelson, Jr et al. '980. The combination of Harwin and Wixon disclose the claimed apparatus except for a worm gear. Axelson [Axelson]

disclose an apparatus with a gear capable of functioning as a worm gear (18), that can provide movement appropriate to the claim language (see also Col. 5, lines 1-9, and line 66 through Col. 6, line 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to construct the device of Harwin et al. and Wixon having at least a worm gear in view of Axelson to better adjust and use the device and better fit the condylar portion of the femur.

***Allowable Subject Matter***

All previous allowability has been withdrawn in view of the new grounds of rejection found above.

***Response to Arguments***

Applicant's arguments with respect to all pending claims have been considered but are moot in view of the new ground(s) of rejection.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James L. Swiger whose telephone number is 571-272-5557. The examiner can normally be reached on Monday through Friday, 9:00am to 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLS

  
EDWARD J. ROBERT  
SUPERVISORY PATENT EXAMINER